

AWARD NUMBER: W81XWH-12-2-0117

TITLE: Project VALOR: Trajectories of Change in PTSD in Combat-Exposed Veterans

PRINCIPAL INVESTIGATOR: Terence M. Keane, PhD

CONTRACTING ORGANIZATION: Boston VA Research Institute
Boston, MA 02130

REPORT DATE: October 2014

TYPE OF REPORT: Annual

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE				Form Approved OMB No. 0704-0188	
Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.					
1. REPORT DATE October 2014		2. REPORT TYPE Annual		3. DATES COVERED 30 Sep 2013 - 29 Sep 2014	
4. TITLE AND SUBTITLE Project VALOR: Trajectories of Change in PTSD in Combat-Exposed Veterans				5a. CONTRACT NUMBER	
				5b. GRANT NUMBER W81XWH-12-2-0117	
				5c. PROGRAM ELEMENT NUMBER	
6. AUTHOR(S): Terence M. Keane, PhD email: Terry.Keane@va.gov Michelle Bovin, Ph.D.				5d. PROJECT NUMBER	
				5e. TASK NUMBER	
				5f. WORK UNIT NUMBER	
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES) Boston VA Research Institute Inc. 150 South Huntington Ave Boston, MA 02130				8. PERFORMING ORGANIZATION REPORT	
9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES) U.S. Army Medical Research and Materiel Command Fort Detrick, Maryland 21702-5012				10. SPONSOR/MONITOR'S ACRONYM(S)	
				11. SPONSOR/MONITOR'S REPORT NUMBER(S)	
12. DISTRIBUTION / AVAILABILITY STATEMENT Approved for Public Release; Distribution Unlimited					
13. SUPPLEMENTARY NOTES					
14. ABSTRACT This goal of this project is to develop a large-scale, longitudinal registry of PTSD in combat-exposed OIF/OEF/OND male and female veterans. The objective of the current study is to systematically expand the longitudinal assessment by collecting follow-up data at additional time points for multiple domains of interest. Patterns of longitudinal change in the VALOR cohort will be empirically classified into trajectory subtypes by means of latent growth mixture modeling. The availability of comprehensive data on PTSD symptoms and related exposures and outcomes at multiple time points in a cohort of VA users with and without PTSD provide a unique opportunity to examine a number of hypotheses regarding longitudinal trajectories in combat-exposed veterans. In addition, the large proportion of women in our sample will allow us to examine variation in the associations by gender.					
15. SUBJECT TERMS Risk factors for PTSD, PTSD symptom development, VA healthcare utilization.					
16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON: USAMRMC
a. REPORT	b. ABSTRACT	c. THIS PAGE			19b. TELEPHONE NUMBER (include area code)
Unclassified	Unclassified	Unclassified	Unclassified	7	

Table of Contents

	<u>Page</u>
1. Introduction.....	4
2. Keywords.....	4
3. Overall Project Summary.....	4
4. Key Research Accomplishments.....	4
5. Conclusion.....	5
6. Publications, Abstracts, and Presentations.....	5
7. Inventions, Patents and Licenses.....	6
8. Reportable Outcomes.....	6
9. Other Achievements.....	6
10. References.....	7
11. Appendices.....	7

1. INTRODUCTION:

Project VALOR is a large-scale, longitudinal registry of PTSD in combat-exposed OIF/OEF/OND male and female veterans. The objective of the current study is to systematically expand the longitudinal assessment by collecting follow-up data at additional time points for multiple domains of interest. Patterns of longitudinal change in the VALOR cohort will be empirically classified into trajectory subtypes by means of latent growth mixture modeling. The availability of comprehensive data on PTSD symptoms, related exposures, and outcomes at multiple time points in a cohort of VA users with and without PTSD provides a unique opportunity to examine a number of hypotheses regarding longitudinal trajectories in combat-exposed veterans. In addition, the large proportion of women in our sample will allow us to examine variation in the associations by gender.

Using baseline and follow-up data from participants in Project VALOR, we will evaluate the following specific aims:

1. Examine trajectories of PTSD symptomatology and diagnosis by chart and diagnostic interview assessments in combat-exposed men and women.
2. Examine the nature and extent of military sexual trauma (MST) in combat-exposed men and women who have utilized the VA Healthcare System, including the contribution of MST to PTSD symptoms and diagnosis.
3. Examine associations of PTSD, mTBI, major depressive disorder (MDD), and treatment utilization in relation to changes in suicidal ideation.

2. KEYWORDS:

Post-traumatic stress disorder (PTSD), military sexual trauma (MST), suicide, combat-exposed veterans, PTSD trajectory, longitudinal, VA utilization

3. OVERALL PROJECT SUMMARY:

In quarter one of this year, 511 participants were consented to participate in the study and 381 subjects completed their participation in the first phase (consisting of an online questionnaire and telephone interview). By the end of quarter two, a total of 1168 subjects were consented to participate and 933 subjects had completed the study. At the end of quarter three, a total of 1448 participants were consented and 1268 subjects had completed the study. In quarter four, we completed the first round of data collection. Out of the total Project VALOR sample (n=1649), 1460 participants (88.5%) were consented for participation and 1348 participants (81.7%) completed their participation in the first phase of the study. In total, 49 participants (3% of the sample) declined to participate in the study. To date, all of the data from the first round of data collection has been entered and we are in the process of cleaning that data for use in future analyses. In September of 2014, we started recruitment for the second round of data collection. To date, 98 participants have agreed to participate and 61 participants have completed their participation in the second round of data collection. Throughout the year, we have continued to analyze data from the first Project VALOR grant for multiple manuscripts and presentations.

4. KEY RESEARCH ACCOMPLISHMENTS:

Nothing to report.

5. CONCLUSION:

The PTSD registry will provide information to assist researchers, military leaders, and treatment providers to better understand PTSD and related problems, with specific focus on the course of the disease, suicidal ideation, and military sexual trauma. This knowledge will be of benefit to health care providers, policy makers and current service members as well as victims of trauma in the broader community. It will include:

- Evaluation of long-term outcomes of PTSD;
- A more accurate assessment of current theoretical models of symptom development, and;
- Documentation of health resource utilization and development of a database that would serve as a resource for health services planning and policy.

Furthermore, this study will contribute:

- The formation of a potential cohort of subjects for ancillary studies, ranging from genomic influences to quality of life and psychosocial outcomes, as well as future clinical trials;
- The creation of a representative sample of PTSD OEF/OIF Veterans who use the VA medical system, available for use in epidemiologic studies, particularly for comparisons with active duty and other Veteran or civilian populations;
- Utility to clinicians, patient advocacy groups, and health policy planners;
- Publications and dissemination of the registry results to provide a representative perspective of what is achieved in actual current care settings, thereby augmenting outcomes data from clinical trials.

6. PUBLICATIONS, ABSTRACTS, AND PRESENTATIONS:

PUBLICATIONS

- Holowka, D. W., Marx, B. P., Gates, M. A., Litman, H. J., Ranganathan, G., Rosen, R. C., & Keane, T. M. (2014). PTSD diagnostic validity in Veterans Affairs electronic records of Iraq and Afghanistan veterans. *J Consult Clin Psychol*, 82(4), 569-579. doi: 10.1037/a0036347
- Wolf, E., Miller, M., Kilpatrick, D., Resnick, H., Badour, C., Marx, B., . . . Friedman, M. (in press). ICD-11 Complex PTSD in US National and Veteran Samples: Prevalence and Structural Associations with PTSD. *Clinical Psychological Science*.
- Miller, C., Wolf, E., Kilpatrick, D., Resnick, H., Badour, C., Marx, B., . . . Friedman, M. (under review). The impacts of proposed changes to ICD-11 on estimates of PTSD prevalence and comorbidity relative to DSM-5 and ICD-10 criteria. *American Journal of Psychiatry*.

PRESENTATIONS

- Bovin, M., Green, J., Marx, B., Keane, T., & Rosen, R. (2014). *The association between military trauma types and psychopathology among OIF/OEF veterans*. Paper accepted for presentation at the 30th Annual Meeting of the International Society for Traumatic Stress Studies, Miami, FL.

- Engel-Rebitzer, E., Bovin, M., Marx, B., Rosen, R., & Keane, T. (2014a). *Peritraumatic Numbness and Posttraumatic Stress Disorder*. Poster presented at the Department of Veterans Affairs Research Week, Boston, MA.
- Engel-Rebitzer, E., Bovin, M., Marx, B., Rosen, R., & Keane, T. (2014b). *Peritraumatic Numbness as a Longitudinal Predictor of PTSD and MDD*. Poster accepted for presentation at the Association for Behavioral and Cognitive Therapies, Philadelphia, PA.
- Engel-Rebitzer, E., Holowka, D., Rosen, R., Marx, B., & Keane, T. (2013). *Peritraumatic Anger and Current PTSD*. Poster presented at the Second Annual BUMC and VA Boston Joining Forces TBI/PTSD Conference, Boston, MA.
- Engel-Rebitzer, E., Marx, B., Szafranski, D., Gallagher, M., Holowka, D., Rosen, R., & Keane, T. (2014). *Race as a Predictor of Concordance between PTSD Diagnosis and Service Connection for PTSD*. Poster presented at the 7th Annual Anxiety and Depression Association of America Conference, Chicago, IL.
- Engel-Rebitzer, E., Marx, B., Szafranski, D., Gallagher, M., Rosen, R., & Keane, T. (2014). *Predictors of Concordance and Discordance between PTSD Diagnosis and Service Connection for PTSD*. Paper accepted for presentation at the 30th Annual Meeting of the International Society for Traumatic Stress Studies, Miami, FL.
- Kulish, A., Holowka, D., Marx, B., Fang, S., Rosen, R., & Keane, T. (2013). *The Influence of Race/Ethnicity and Gender on Psychosocial Functioning in Combat-Exposed Veterans Post- OEF/OIF Deployment*. Poster presented at the 47th Annual Convention, Association for Behavioral and Cognitive Therapies, Nashville, TN.
- Ledoux, A., Green, J., Harte, C., Marx, B., Rosen, R., & Keane, T. (2014a). *Associations between posttraumatic stress, TBI and sexual function in male OIF/OEF veterans*. Poster presented at the Department of Veterans Affairs Research Week, Boston, MA.
- Ledoux, A., Green, J., Harte, C., Marx, B., Rosen, R., & Keane, T. (2014b). *Posttraumatic stress disorder symptom severity as a predictor of sexual function in OIF/OEF veterans*. Poster presented at the 7th Annual Anxiety and Depression Association of America, Chicago, IL.
- Ledoux, A., Green, J., Harte, C., Marx, B., Rosen, R., & Keane, T. (2014c). *Symptoms of PTSD as Predictors of Sexual Function in OIF/OEF Veterans*. Poster accepted for presentation at the 48th Annual Convention of the Association for Behavioral and Cognitive Therapies, Philadelphia, PA.

7. INVENTIONS, PATENTS AND LICENSES:

Nothing to report

8. REPORTABLE OUTCOMES:

Nothing to report

9. OTHER ACHIEVEMENTS:

Three proposals that extend Project VALOR's work on the prediction of risk for suicidality are awaiting funding. The first two, entitled "Establishing an Empirically-

Based Method for Assigning Suicide Risk Status” and “Developing a Multidimensional Suicide Risk Profiling System for Returning Veterans” have been accepted into a larger proposal to fund the VA Patient Safety Center of Inquiry for Suicide Prevention. They will work in tandem to examine large VA databases (Suicide Prevention Applications Network or SPAN and the VA Corporate Data Warehouse or CDW) to develop and test an empirically based approach to designating level of suicide risk, including the identification of suicide risk profiles using latent profile analysis.

The third project is awaiting funding from the VA Quality Enhancement Research Initiative (QUERI) Rapid Implementation Supplements for Operations and Methodological Enhancements (RISOMEs) mechanism, and is entitled, “Enhancing Suicide Risk Prediction Systems across VA and Private Healthcare Settings”. This project will combine the efforts of the previous two proposals with a third, similar study to be conducted in not-for-profit civilian hospital systems. These three projects will be collecting data and building risk calculation algorithms simultaneously. Through shared knowledge and an iterative approach, an overarching risk prediction model, using information from all three projects, will be developed with the ultimate goal of implementation across all healthcare systems involved. This greatly expands the generalizability and potential national reach of these projects.

10. REFERENCES

N/A

11. APPENDICES

N/A